

Message Text

UNCLASSIFIED

PAGE 01 STUTTG 01460 311505Z
ACTION HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-07 /026 W
-----130741 311549Z /40
P 311430Z AUG 76
FM AMCONSUL STUTTGART
TO SECSTATE WASHDC PRIORITY 3788

UNCLAS STUTTGART 1460

PASS FDA

E.O. 11652: N.A.
TAGS: OGEN, ETRD, EJND, TBIO, GW
SUBJ: FDA ADVISORY (RECALL NUMBER B012-7)
REF: STATE 203605; STUTTGART 1239; STATE 130061

CONTACTED BOEHRINGER, MANNHEIM RE CONTAINERS 82-167 BEING
HBSAG REACTIVE. HERR HEBSACKER REITERATED HIS FIRM TOLD
BY DELIVERY FIRM (BPC) THAT BOTTLES SHIPMENT 506 1-81
HBSAG POSITIVE BUT BOTTLES 82-167 HBSAG NEGATIVE (CHARGE
506-2). BOEHRINGER THEMSELVES TESTED BOTTLES IN QUESTION
ACCORDING TO STRICT GERMAN LAW AND CAME TO SAME RESULT:
HBSAG NEGATIVE FOR NUMBERS 82-167.

RIA-TEST USING ABO TT TEST KIT AUSRIA II 125 OBTAINED
FOLLOWING RESULTS:

POOL NUMBER	P/N RATIO
-------------	-----------

1	1.7
2	1.6
3	1.6
4	1.4
5	1.7
6	1.7
7	1.6
8	1.8

UNCLASSIFIED

UNCLASSIFIED

PAGE 02 STUTTG 01460 311505Z

9	1.6
10	1.4
11	1.7
12	1.8
13	1.6
14	1.4

15 1.5

16 1.8

17 1.7

TOTAL POOL 1.6

POOL NUMBERS: OUT OF EVERY 10 BOTTLES, ONE MILLILITER
SERUM TAKEN AND MIXED; RIA TEST THEN PERFORMED ON THIS.

TOTAL POOL: ONE MILLILITER TAKEN FROM EVERY BOTTLE AND
MIXED WITH THE OTHERS AND TEST PERFORMED.

BOEHRINGER CONSIDERS ITS TESTS, AND BPC REPORT SHOW
BOTTLES 82-167 TO BE SAFE.

BOEHRINGER STATED IN LIGHT OF AGREEMENT REACHED BETWEEN
BPC AND FDA THAT BOTTLES 82-167 HBSAG NEGATIVE, SHIPMENT
WAS PROCESSED FOR RELEASE TO THE MARKET.

DOES FDA ACCEPT THIS AS SETTling MATTER? IF NOT, DOES
FDA HAVE INFORMATION ENABLING CONGEN TO AGAIN CONTACT
BOEHRINGER?

IN VIEW OF EMPHATIC ASSERTIONS OF SHIPMENT SAFETY CONGEN
AT LOSS TO RETURN TO FIRM WITHOUT SUBSTANTIVE GUIDANCE.
JENKINS

UNCLASSIFIED

NNN

*** Current Handling Restrictions *** n/a

*** Current Classification *** UNCLASSIFIED

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 31-Aug-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STUTT01460
Document Source: CORE
Document Unique ID: 00
Drafter: n/a
Enclosure: n/a
Executive Order: n/a
Errors: n/a
Expiration:
Film Number: D770315-0093
Format: TEL
From: STUTTGART
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t197708113/aaaafykd.tel
Line Count: 85
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON MICROFILM, TEXT ON-LINE
Message ID: 197cb350-c288-dd11-92da-001cc4696bcc
Office: ACTION HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: 77 STATE 203605, 77 STUTTGART 1239, 77 STATE 130061
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 09-Dec-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 1441916
Secure: OPEN
Status: <DBA CORRECTED> gwr 970911
Subject: FDA ADVISORY (RECALL NUMBER B012-7)
TAGS: EIND, ETRD, OGEN, TBIO, GE, US, OGEN
To: STATE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/197cb350-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009